

REMARKS

Upon entry of the foregoing amendment, Claims 1-23, and 26-28 remain pending in the above-identified application. Claims 24 and 25 have been canceled without prejudice and Applicants reserve the right to pursue the subject matter recited in Claims 24 and 25 in a continuation application. Applicants have added new Claims 27 and 28.

Rejection of the Claims Under 35 USC § 103

Claims 1-7, 16-23 and 26

Claims 1-7, 16-23 and 26 stand rejected under 35 USC § 103(a) as being unpatentable over D'Antonio (U.S. Patent No. 5,810,831). Applicants respectfully traverse these rejections.

D'Antonio discloses a femoral sizing guide having a sizing guide block 22 that can be positioned adjacent a distal end 16 of a femur 10, from which a distal portion 14 has been removed. *See* '831 patent at Col. 4, lines 1-10; Figure 1 (reproduced below).

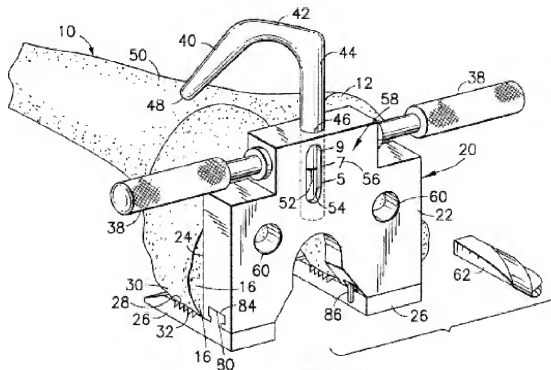
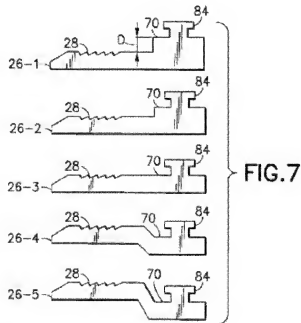


FIG.2

The guide also has removable locator feet 26 for engaging the posterior condyles 30 to assist in the location of a femoral cutting guide of suitable size. *See* '831 patent at Col. 4, lines 18-42; Figure 1. The guide block 22 has drill guide openings 60 to guide a drill 62, "thereby assuring the appropriate subsequent location of the femoral cutting guide on the distal femur."

'831 patent at Col. 4, lines 57-62. The locator feet 26 can be chosen from a variety of sizes, and are removably coupled to the guide block 22 to "space the openings 60 in the sizing guide block 22, in the anterior/posterior direction, by a corresponding selected amount." '831 patent at Col. 5, lines 12-35; Figure 7 (reproduced below).



The surgeon can therefore interoperatively change the locator feet 26 to change the femoral sizing guide dimensions. '831 patent at Col. 2, lines 15-30; col. 5, lines 12-42.

The Examiner asserts that though D'Antonio fails to disclose a template having a support part and a flank that contacts the dorsal part of the femoral condyles defined as a single piece, it would have been obvious to modify the disclosed sizing guide in D'Antonio to have a guide block 22 and locator feet 26 defined by a single piece. *See* Office Action, page 3. Applicants respectfully disagree.

Applicants respectfully submit that D'Antonio clearly teaches away from using a template where a support part and flank that contacts the dorsal part of the femoral condyles are defined by a single piece. In fact, D'Antonio points out that "the fixed location between the locator feet and the sizing guide block can restrict the ability to compensate for various conditions encountered at the implant site, with the result that the selection of a particular femoral sizing guide can lead to some compromises in the location of the implanted femoral knee prosthesis." D'Antonio at col. 1, lines 41-51. D'Antonio goes on to state that it's modular sizing guide, which has locator feet that can be chosen from a variety of sizes and removably coupled to the sizing guide block,

“enables the surgeon, interoperatively, to compensate for conditions encountered at the implant site when utilizing a femoral sizing guide to determine the size of the femoral knee prosthesis to be implanted.” D’Antonio at col. 2, lines 15-19. Accordingly, D’Antonio teaches away from using a sizing guide where the locator feet and guide block are defined by one piece, so that a prima facie case of obviousness cannot be established by modifying D’Antonio as suggested by the Examiner. As noted by the Supreme Court’s decision in *KSR Int’l. v. Teleflex, Inc.*, a finding of nonobviousness is more likely when the prior art references teach away from a combination of elements. See *KSR Int’l. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740 (2007).

Moreover, modifying D’Antonio to include a template with a support part and a flank defined as a single piece, or permanently connected to each other, would frustrate the purpose of the modular sizing guide disclosed and taught by D’Antonio, which D’Antonio states overcomes the disadvantages of using a single piece sizing guide. Thus, such a modification of the modular sizing guide in D’Antonio would render D’Antonio unsatisfactory for its intended purpose, and therefore a prima facie case of obviousness cannot be established. See M.P.E.P., §2143.01V.

Additionally, as further discussed below, Applicants respectfully submit that D’Antonio does not disclose or teach, among other things, resecting more bone from the femoral condyles than is replaced by the femoral slideway prosthesis. As discussed at the recent interview, D’Antonio fails to teach or suggest the undersizing of the femoral slideway relative to the unresected femur, as recited, for example, in Claims 1, 16 and 26.

Figure 4 of Applicant’s specification illustrates one non-limiting embodiment, reproduced below, wherein a femur-size template is used to locate the previously-determined distance “e” from a peg-hole and condyles of an unresected femoral bone.

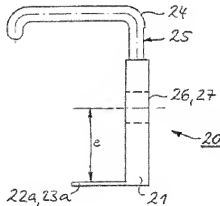
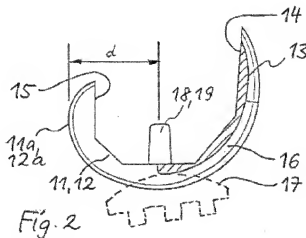


Fig. 4

The femur-size template (20) has a basic or support part 21 and contact surfaces or flanks (22a, 23a), with a bore (26, 27) extending through the support part (21) at a previously determined distance "e" from the contact surfaces (22a, 23a). Once the peg-hole is drilled through the bore (26, 27) while the support part (21) and contact surfaces (22a, 23a) of the template engage the unresected condyles of the femur, a slideway, such as shown in Figure 2, is selected, which has a distance "d" defined between the outermost posterior points on the distal sliding surfaces (11a, 12a) and the long axis of the pegs (18, 19). The distance "e" between the bores (26, 27) and the contact surfaces (22a, 23a) is not adjustable (i.e. the support part (21) and flanks (22a, 23a) are a single piece), nor are the contact surfaces (22a, 23a) detachable from the femur-size template or adjustable to accommodate variations in femur anatomy.



This slideway is selected such that the distance "e" is greater than the distance "d", indicating that more bone has been resected dorsally on the femur than will be replaced by the thickness of the dorsal parts of the condyle shells, as shown in Figure 5b below. Additionally, as illustrated in the non-limiting embodiment shown in Figure 5b, both the medial and lateral condyles are resected by an equal amount greater than that replaced by the dorsal parts of the condyle shells of the slideway prosthesis. Such "over-resection" in comparison to the original dimensions of the unresected condyles or to a conventional femoral slideway, reduces the load on the collateral ligaments. As described in the non-limiting embodiment on page 2, line 29 – page 3, line 9 of the specification, the distance "e" can be greater than the distance "d" by 5-15%, and in particular by about 10%. Moreover, because the peg-hole location was predetermined by use of

the femur-size template, the slideway's position is also predetermined relative to the original, unresected femur.

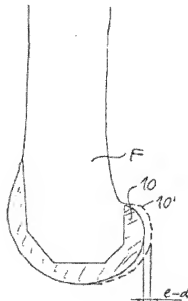


Fig. 5b

D'Antonio does not disclose resecting more bone on dorsal condyles of a femur (e.g., on the medial and lateral condyles) than is replaced by the slideway prosthesis, as illustrated, for example, in the non-limiting embodiment shown in Figure 5b, above. Instead, D'Antonio discloses the possibility of removing "more or less bone from a particular posterior condyle than that which is dictated by the fixed locator feet of a selected femoral sizing guide in order to compensate for a particular condition observed interoperatively." D'Antonio at col. 1, lines 52-55. Such conditions include the need to equalize the flexion/extension gap if more bone was resected from the femoral distal end, absent cartilage on a worn posterior condyle, or erosion or atrophy, which could cause unstable seating of the femoral sizing guide. However, none of these conditions involve resecting more bone from the dorsal side of the femur than is replaced by the femoral prosthesis, as recited in the claims of the above-identified application.

In view of the foregoing, Applicants respectfully submit that the Examiner has not presented a prima facie case of obviousness, and that independent Claims 1, 16 and 26 are patentable over D'Antonio. Claims 2-7 depend from Claim 1, and Claims 17-23 depend from Claim 16. Accordingly, Applicants respectfully submit that Claims 2-7 and 17-23 are likewise patentable over D'Antonio, not only because these claims depend from an allowable base claim,

but also because each of these claims recites a unique combination of features not taught in the cited art.

Claim 8

Claim 8 stands rejected under 35 USC § 103(a) as being unpatentable over D'Antonio in view of Colleran (U.S. Pat. No. 5,776,201). Applicants respectfully traverse this rejection.

The Examiner asserts that "Colleran teaches the femoral prostheses are different sizes, col. 2, lines 54-56," and argues that "it would have been obvious to one of ordinary skill in the art to use a plurality of femoral prostheses as taught by Colleran et al. in D'Antonio's method of surgery on a femur such that the surgeon has a proper fitting for the patient since all patients are going to have different anatomical features." Office Action, pages 4-5.

As discussed above, Applicants respectfully submit that amended Claim 1 is patentable over D'Antonio. Claim 8 depends from Claim 1 and is therefore likewise patentable over D'Antonio, alone or in combination with the cited references, not only because it depends from an allowable base claim, but also because it recites a unique combination of features not taught in the cited art.

Additionally, Claim 8 recites, among other limitations, that "**all** of the slideways in said group have **substantially equal peg-to-sliding surface dimensions** as defined by a perpendicular distance between a longitudinal axis of a peg extending from the slideway and a plane tangent to a dorsal sliding surface furthest away from the peg, each slideway in said group has a different dorsal condyle-to-ventral condyle distance." Colleran, alone or in combination with D'Antonio, does not teach these features. In particular, Colleran at most teaches femoral implants with different anterior-posterior lengths. *See* Colleran, Col. 2, lines 54-67. However, Colleran does not teach or suggest a group of slideways, wherein **all** of the slideways in the group have **substantially equal peg-to-sliding surface dimensions**, each slideway in said group having a different dorsal condyle-to-ventral condyle distance. Colleran does not even discuss a distance between sliding surfaces defined by a plane tangent to the dorsal condyles and an axis extending along pegs of the slideway, much less that such a distance is substantially equal among all of the slideway prostheses. The peg-to-sliding surface dimension is illustrated in the non-limiting embodiment shown in Figure 2 of Applicant's specification as a distance "d," whereas the dorsal

condyle-to-ventral condyle distance is illustrated in the non-limiting embodiment shown in Figure 1 of Applicant's specification as a distance "a."

In view of the foregoing, Applicants respectfully submit that the Examiner has not presented a prima facie case of obviousness with respect to Claim 8 and respectfully requests withdrawal of this rejection.

Claims 9-15

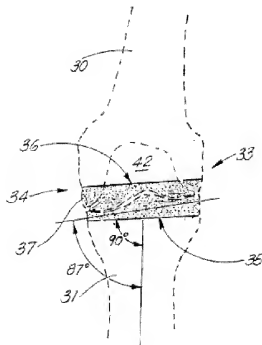
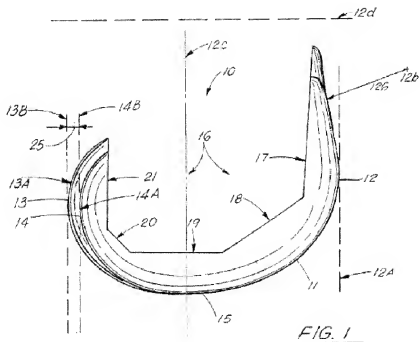
Claims 9-15 stand rejected under 35 USC § 103(a) as being unpatentable over D'Antonio in view of Ries (U.S. Patent. No. 5,549,688). Applicants respectfully traverse these rejections.

Applicants respectfully submit that D'Antonio does not disclose, teach or suggest, among other things, "resecting bone material from said femur, wherein said resecting includes removing more bone material from a dorsal side of the femur than will be replaced by the slideway to allow for a reduction of the distance between the peg and a center of the turning radius of the dorsal portion of the slideway compared to the unresected femur to reduce a load on ligaments attached to the femur," as recited, among other limitations, in Claim 9. Moreover, D'Antonio does not disclose "indicating a point at a previously-determined distance from a dorsal most point of said femur, wherein said previously-determined distance is 5 to 15% larger than a distance between a peg and a dorsal sliding surface of the femoral slideway to be implanted on the femur bone," as recited, among other limitations, in Claim 9.

The Examiner agrees that "D'Antonio fails to disclose the bone material removed is done to reduce the load on ligaments attached to the femur." Office Action, page 5. However, the Examiner states that "Ries et al. teach that removal of bone is greater than the slideway such that it reduces the load on the ligaments and balancing the strain relationship with the prosthesis and bone, col. 1, lines 43-45, col. 4, lines 51-52." *Id.* Applicants respectfully disagree.

Ries discloses that conventional knee arthroplasty results in a 90° cut in the tibia relative to its axis, which results in more bone being removed from the lateral side than the medial side of the tibia. *See* Ries, col. 1, lines 28-29; Fig. 4, reproduced below. Where "neutral femoral cuts are performed, and implants with equal medial and lateral thicknesses are used, there is a laxity of the lateral and collateral ligament at ninety-degrees of flexion". *Id.* at lines 31-34 (emphasis added). "The lateral and collateral ligament is lax in flexion because the resection of the tibia and the resection of the femur are not parallel, but the prosthesis implanted has equal medial and lateral

thicknesses on the tibial component and posterior condyles of the femoral components.” *Id.* at lines 34-39 (emphasis added). It is this problem of “laxity” in flexion, not a need to reduce a load on ligaments attached to the femur, that the asymmetrical implant 10 of Ries (Fig. 1, reproduced below) addresses.



Therefore, Applicants respectfully submit that D'Antonio and Ries, alone or in combination, do not disclose, teach or suggest, "resecting bone material from said femur, wherein said resecting includes removing more bone material from a dorsal side of the femur than will be replaced by the slideway to allow for a reduction of the distance between the peg and a center of the turning radius of the dorsal portion of the slideway compared to the unresected femur to reduce a load on ligaments attached to the femur," as recited in Claim 9. Instead, Ries teaches an asymmetrical implant 10 that does not result in a laxity of the lateral and collateral ligament in flexion. *See* Ries, col. 2, lines 41-42.

Additionally, Applicants respectfully submit that a rejection based on "optimum or workable ranges" is inappropriate where the prior art does not teach or suggest the desirability of the result achieved. As discussed in MPEP § 2144.05, "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." *In re Antonie*, 559 F.2d 618, 195 U.S.P.Q. 6 (CCPA 1977). Thus, for a rejection to be made based on "optimum or workable ranges," the prior art must first identify the result which the variable achieves. Without D'Antonio, alone or in combination with Ries, teaching the desired results of reducing the distance between the peg and center of the turning radius of the dorsal portion of the slideway in order to reduce a load on ligaments attached to the femur, it would not have been merely a matter of design choice, as the Examiner suggests, for the previously-determined distance to be 5 to 15% larger than a distance between a peg and a dorsal sliding surface of the femoral slideway.

Further, with reference to the rejection of Claims 9-15 under 35 U.S.C. § 103(a), Applicants assert that one skilled in the art would not have found a reason to combine the references cited by the Examiner, and that the Examiner has not explicitly articulated any reason why one skilled in the art would have combined the prior art elements in the manner claimed by the Applicants. The Supreme Court's decision on *KSR Int'l. v. Teleflex, Inc.* refines the issue of obviousness under 35 U.S.C. § 103(a) in relation to prior art. *See KSR Int'l. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). The Court noted that the analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit, and that it was "important to identify a reason that would have

prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *Id.* at 1731. The Court specifically stated:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. *See In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

Id. at 1741-42. Accordingly, in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

Contrary to the Supreme Court’s decision in *KSR*, the Examiner has failed to set forth “explicit” reasons to combine the foregoing references. Specifically, the Examiner makes only a cursory mention of Ries and therefore, the Examiner has not made explicitly clear what from Ries that he is combining with Gilson. Further, the Examiner has failed to point out any reason for why one skilled in the art would make the proposed combination.

In fact, Applicant submits that one skilled in the art would not have reason to make the proposed combination. As noted above, Ries is directed to an asymmetrical implant 10 that does not result in a laxity of the lateral and collateral ligament in flexion. *See Ries*, col. 2, lines 41-42 (emphasis added). Ries is not directed to reduction of a load on ligaments attached to the femur, as recited, among other recitations, in Claim 9. And, as the Examiner acknowledges, D’Antonio also “fails to disclose the bone material removed is done tot reduce the load on ligaments attached to the femur.” Office Action, page 5. Accordingly, since neither D’Antonio nor Ries teaches reduction of a load on ligaments attached to the femur, one of ordinary skill in the art would have no reason to combine the two references.

Thus, Applicants submit that D’Antonio, alone or in combination with Ries, fails to teach or suggest the unique features described above, and in particular, those recited in Claim 9. For the reasons discussed above, Applicants respectfully submit that Claim 9 is patentable over D’Antonio, alone or in combination with Ries. Claims 10-15 depend from Claim 9 and are

therefore likewise patentable over D'Antonio, alone or in combination with Ries, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught in the cited art.

Rejection of the Claims Under 35 USC § 102

Claims 24 and 25

Claims 24 and 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by D'Antonio. Applicants have canceled these claims without prejudice and reserve the right to pursue the subject matter in these claims in a continuation application.

New Claims 27 and 28

Applicants have added new Claims 27 and 28, which depend from Claims 9 and 16, respectively. Applicants respectfully submit that Claims 27 and 28 are allowable over D'Antonio, alone or in combination with the cited art, not only because they depend from allowable base claims, but also because each of these claims recites a unique combination of features not taught in the cited art.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion or that the limitation discussed is essential or critical; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence, disclaimer or estoppel is intended or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicants may not have presented in all cases, arguments concerning whether the applied references can be properly combined or modified in view of the deficiencies noted above, and Applicants reserve the right to later contest whether a proper motivation and suggestion exists to combine or modify these references.

Appl. No. : 10/616,102
Filed : July 9, 2003

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: July 6, 2007

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AMEND

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